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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,498	08/16/2001	Emmanuel Lazaridis	114205.204	2508
21901	7590	01/24/2006	EXAMINER	
SMITH & HOPEN PA 15950 BAY VISTA DRIVE SUITE 220 CLEARWATER, FL 33760			LIN, JERRY	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,498

Applicant(s)

LAZARIDIS, EMMANUEL

Examiner

Jerry Lin

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) 7-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11-18, 24 and 25 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed November 9, 2005, have been fully considered and they are deemed to be persuasive in part. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 15, 17, 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The formula in claims 2 and 3 are not fully described as to the parameter of "K". The Examiner must read the claims with the broadest reasonable interpretation. The applicant has stated that the specification makes it clear the number of dimensions in the multidimensional space depends upon the number of measurements used in

analysis. However, the Examiner cannot import limitation from the specification into the claims. Thus, the parameter "K" remains indefinite as to its metes and bounds.

Claims 17 recite the limitation "the variables". There is insufficient antecedent basis for this limitation in the claim. The term "variables" was not mentioned previously in the instant claims or in the claim from which it depends.

Claims 24 and 25 recite the limitation "said objects". There is insufficient antecedent basis for this limitation in the claim. The term "objects" was not mentioned previously in the instant claims or in the claim from which it depends.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 4, 6, 11, 13, and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by Alon et al. (PNAS, Vol 96, pages 6745-6750).

Regarding claim 1, 4, 6, and 18 Alon et al. teach identifying at least one gene of interest related to the medical condition and providing observations of the gene (page 6749, right column; page 6745); assigning at least one observation on the gene to form a first dimension of a matrix (page 6746, right column, Figures 2-3); acquiring a sample from a host, providing a least one observation on the sample, assigning the observation

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to the matrix to form a second dimension (page 6745, Figures 1-3); identifying as least one latent class of each gene in a first dimension and identifying at least one latent class of each sample in a second dimension (page 6745, right column); calculating the likelihood that at least one gene of interest belongs to the identified class in the first dimension, and calculating the likelihood that at least one sample of interest belongs to the identified class in the second dimension (page 6746, right column, page 6749, left column); identifying the gene as being linked to the medical condition based upon likelihood calculations and identifying the medical condition (page 6745). Alon et al. also teach wherein the cellular phenotype is a disease (page 6745)

Regarding claim 11, Alon et al. teach extracting expression and position information from an array to generate data (page 6745), assigning in a computer to each dimension of a gene or cluster of genes a numerical value (page 6746); generating in a computer an information algorithm for said extracted information to provide a linking pattern for said gene or cluster of genes (page 6746, right column - page 6749).

Regarding claim 13, Alon et al. teach providing nucleic acid material from a suspected cancerous sample (page 6745, right column); hybridizing the sample derived process to the library (page 6745, right column); detecting the differences between the hybridization results and the reference standard (page 6749, left column); recording the differences to form a first set of data (page 6749); assigning the first set of data to form a first dimension (page 6749); analyzing protein expression data to form a second set of data (page 6745); assigning the second set of data to form a second dimension of the

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matrix (page 6745); combining the first and second set of data to identify the gene or set of genes which govern metastatic properties of cancer (pages 6749-6750).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 6, 12, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alon et al. (PNAS, Vol 96, pages 6745-6750), in view of Lazaridis, (Dissertation Thesis, The University of Chicago, IL, December 1994) further in view of Skene et al. (Statistics in Medicine, Vol 11, pages 2111-2122).

Alon et al. is applied as above.

Regarding claims 5, 6, 12, Lazaridis teaches a model used for statistical analysis of a sample comprising N objects each of which as a J measured characteristics (page 1). His model associates people with attributes (abstract). The data for each object consists of measurements (e.g. laboratory tests). Lazaridis modeled a cluster in the data by latent class (page 4). Lazaridis' model associates a patient with a disease and characterizing the disease by comparing data from a patient with a standard (pages 6-7). Lazaridis discloses a latent class formula similar to that of the instant invention (page 7) wherein μ and σ are the latent class parameters similar to $(t_{ij}, \alpha, \beta, \gamma, \sigma)$ of the instant claim (page 9, 37, and 38). Lazaridis also discloses calculating a likelihood that

an object belongs to a subset of particular characteristic (e.g. pages 37 and 78).

Lazaridis illustrates this model on the thyroid data consisting of the results of five laboratory tests specific for thyroid disease obtained from 215 patients (page 114).

However, Lazaridis does not specifically disclose parameter estimation in two directions.

Skene et al. teach a latent class model for repeated experimental measurements wherein a specific response is measured at a particular time (a two directional experiment) (page 2113). Skene et al. disclose parameters of the response (μ_{jm} , δ_{il} , ρ_{ij} , σ^2) (page 2441).

Regarding claim 16, Skene et al. teach exposing a cell to a drug (page 2111).

Regarding claim 17, Skene et al. teach registering measured observations associated with a disease at a zero time (page 2111, 2117).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Alon et al. to apply the models of Lazaridis and Skene et al.. One of ordinary skill in the art would have been motivated to combine the teachings to gain the advantage of an improved correlation of data obtained from an object and an attribute, as taught by Lazaridis (Abstract) and Skene et al. (page 2120).

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alon et al. (PNAS, Vol 96, pages 6745-6750) in view of Assa et al. (Proceedings of the 8th IEEE Visualization '97 Conference).

Alon et al. is applied as above.

Furthermore, Alon et al. teach wherein a parameter is the amount of nucleic acid (page 6745-6746).

Alon et al. does not specifically teach a third data set of parameters.

Assa et al. teach building multidimensional matrices with multiple sets of data (Abstract).

It would have been obvious for one of ordinary skill in the art at the time of the invention to record a third set of parameters into Assa et al.'s matrix for the purpose of identifying genes related to cancer as in Alon et al. Assa et al. teach that their method offers the advantage of analyzing various classes of data objects, determining the relevance of the rules to those classes, and highlighting the relationship between data objects (page 127). Thus one of ordinary skill in the art would be motivated to incorporate the references of Assa et al. with Alon et al. to gain the benefit of a method that highlights the relationship between the classes.

Contact Information

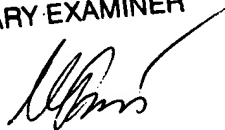
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00am-6:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Representatives are available to answer your questions daily from 6 am to midnight (EST). When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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MICHAEL BORIN, PH.D
PRIMARY EXAMINER



JL